K042517

OCT 8 - 2004

510(k) Summary
Linvatec Biomaterials
Ø 1.5mm and 2.0mm screw models of BioSorb™ FX and BioSorb™ PDX product families

Submitter's Name, Address, Telephone Number, and Contact Person

Linvatec Biomaterials Ltd.
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Date prepared: August 6th, 2004

Name of the device:

A.	Trade or Proprietary Name:	BioSorb™ FX and BioSorb™ PDX 1.5 and 2.0 Screws
B.	Common Name:	Bioabsorbable fixation fasteners, used with plates
C.	Classification Name:	Biodegradable fixation fastener, used with plates (Product code JEY)

Predicate Devices:

The predicate devices are the previously cleared Linvatec Biomaterials (the previous Bionx Implants) diameter 1.5mm and 2.0mm screw type fasteners, which are used with bioabsorbable plates of the same products families BioSorb™ FX 1.5/2.0 (K982139), BioSorb™ FX 2.0/2.4 O/M (K982721, K011569) and BioSorb™ PDX (K000836).

Originally the screw head design of Ø 1.5 and 2.0mm screw models of BioSorb™ FX and BioSorb™ PDX product families was designed as a crosshead screw. Further development of head design for easier insertion of Ø 1.5mm and 2.0mm screw models continued and finally new head design with outer attachment of screw driver was finalized. The main purposes were improvement of installation properties without sacrificing torsion properties of the screw model.

The revision of head design has no effect on intended use, principles of operation, production methods, raw material or sterilization. The screw drivers are revised accordingly, but other parts of instrumentation are remaining unchanged.

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Substantial Equivalence:

The new Ø 1.5 and 2.0mm screw model has the following similarities to the cleared models of BioSorb™ FX 1.5/2.0 (K982139), BioSorb™ FX 2.0/2.4 O/M (K982721, K011569) and BioSorb™ PDX (K000836):

- has the same indicated use
- uses the same operating principle
- incorporates the same basic design of thread
- utilizes the same basic dimensions
- is manufactured by machining
- is packaged and sterilized using the same materials and processes
- has the same shelf life

In summary, the new head design described in this notification is, in our opinion, substantially equivalent to the predicate device.

Contraindications are as follows for Ø 1.5 and 2.0mm screw models of BioSorb™ FX 1.5/2.0 and BioSorb™ PDX product lines:

1. The mandible or continuity defects in load bearing areas
2. Situations where internal fixation is otherwise contraindicated, e.g. active or potential infection; patient conditions, including blood supply limitations, insufficient quantity or quality of bone; and where patient co-operation cannot be guaranteed (e.g. alcoholism).
3. Patients with suspected or known allergy to implant materials.

Contraindications for BioSorb™ FX 2.0/2.4 O/M System product lines are as follows:

1. Mandibular tumor resection
2. Situations where internal fixation is otherwise contraindicated, e.g. active or potential infection; patient conditions, including blood supply limitations, insufficient quantity or quality of bone; and where patient co-operation cannot be guaranteed (e.g. alcoholism).
3. Significant comminuted fractures including significant bone loss of the mandible.
4. Intermaxillary fixation without an appropriate external fixation by other means.
5. Patients with suspected or known allergy to implant materials.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-off

Division of Dental, Infection Control, and General Hospital Devices

510(k) Number K042517

Prescription Use___X_____ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 8 - 2004

Ms. Tuija Annala
Director, Quality and Regulatory Affairs
Linvatec Biomaterials, Limited
P.O. Box 3
Fin-33721 Tampere,
FINLAND

Re: K042517
Trade/Device Name: Ø 1.5mm and 2.0mm BioSorb™ FX and BioSorb™ PDX Screws
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: August 4, 2004
Received: September 15, 2004

Dear Ms. Annala:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

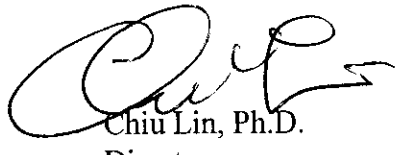
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K042517

Device Name: Ø 1.5mm and 2.0mm BioSorb™ FX and BioSorb™ PDX Screws

Indications for Use:

Ø 1.5 and 2.0mm screw models of BioSorb™ FX and BioSorb™ PDX are used for plate fixation fasteners in trauma and constructive procedures in the midface and craniofacial skeleton. Specifically, the device is indicated for use in treating fractures of the craniofacial skeleton, including, but not limited to, comminuted fractures of the nasoethmoidal and infraorbital areas; comminuted fractures of the frontal sinus wall; orbital floor fractures; trauma of the midface or craniofacial skeleton and reconstructive procedures of the midface or craniofacial skeleton.

Ø 2.0 mm screw models of BioSorb™ FX can be used for plate fixation fasteners with BioSorb™ 2.0/2.4 O/M plates in trauma and reconstructive procedures in the midface, maxilla and mandible. Especially in mandible BioSorb™ FX 2.0/2.4 O/M System must be used in conjunction of appropriate maxillomandibular fixation (MMF).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-off

Division of Dental, Infection Control, and General Hospital Devices

510(k) Number K042517

Prescription Use X OR Over-The-Counter Use

(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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